COVID-19 Vaccine Information Brief

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IMPORTANT/NEW COVID-19 Vaccine Information

- Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older

CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal for Persons Aged 65 Years and Older

For years, U.S. government agencies have used multiple, complimentary safety monitoring systems to help detect possible vaccine statistical signals as early as possible and to facilitate further investigations, as appropriate. As part of routine surveillance, the CDC's Vaccine Safety Datalink detected a safety signal indicating a slight increase in the risk of ischemic stroke in people aged 65 and older who had received the Pfizer BioNTech COVID-19 bivalent booster vaccine within 21 days of the event. Per CDC, the increased risk "just exceeds statistical significance" but triggered further investigation. No increase has been detected associated with the Moderna bivalent booster vaccine.

Investigators have NOT found this in any other safety system databases including the Vaccine Adverse Event Reporting System (VAERS), Veterans Affairs, nor the Centers for Medicare and Medicaid (CMS) data, which is reassuring. The CDC notes the US vaccine safety systems are very sensitive and are designed to pick up any possible risk and this is an example of the system working well to detect signals to be investigated to determine if a risk exists. At this time, experts **believe it is very unlikely this is a clinically relevant risk** and continue to recommend the bivalent Pfizer booster for all authorized age groups. This is being shared because transparency and vaccines safety are top priority. The CDC will post a summary of these findings on its website.

No change in vaccination practice is recommended. CDC continues to recommend everyone ages 6 months of age and older stay up-to-date with COVID-19 vaccination; this includes individuals who are currently eligible to receive an updated (bivalent) vaccine. Staying up-to-date with vaccines is the most effective tool for reducing death, hospitalization, and severe disease from COVID-19, as has now been demonstrated in multiple studies conducted in the United States and other countries.